



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/571,991

03/15/2006

Laurent Francois Andre Hennequin

09963.0008

5523

22852

7590

01/06/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

WILLIS, DOUGLAS M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,991	Applicant(s) HENNEQUIN ET AL.	
	Examiner DOUGLAS M. WILLIS	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-71 is/are pending in the application.
- 4a) Of the above claim(s) 44-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03-15-06; 07-11-06; 01-09-07; 07-14-08; 12-11-08.

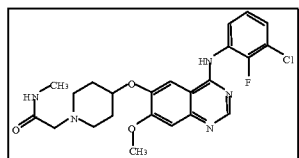
DETAILED ACTION

Status of the Claims / Priority

Claims 38-71 are pending in the current application. According to the *Amendments to the Claims*, filed July 14, 2008, claims 1-37 were cancelled and claims 38-71 were added. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/GB2004/03937, filed September 15, 2004, which claims priority under 35 U.S.C. § 119(a-d) to: a) EP 03292309.6.7, filed September 19, 2003; and b) EP 04291248.5, filed May 14, 2004.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, with traverse, in the reply filed on December 11, 2008, is acknowledged: a) Group I, claims 38-43; and b) substituted



quinazolinamine - p. 58, example 1, shown left, and hereafter referred to as 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(*N*-methylcarbamoylmethyl)piperidin-4-yl]oxy}quinazoline.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 44-71, drawn to a nonelected invention, with traverse, in the reply filed on December 11, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Thus, a second Office action on the merits of claims 38-43 is contained within.

Status of Claim Rejections - 35 U.S.C. § 103

Applicant's arguments, on pages 2-10 of the *Remarks*, filed December 11, 2008, with

Art Unit: 1624

respect to claims 38-43, have been fully considered, but are not persuasive. Consequently, the rejection of claims 38-43 under 35 U.S.C. § 103, made in the *Non-Final Rejection*, mailed on August 19, 2008, is maintained for the reasons of record.

Applicant primarily argues that post-*KSR*, a prima facie case of obviousness for a chemical compound begins with the reasoned identification of a lead compound. Furthermore, applicants argue that there is no rationale to modify the reference example to achieve the species of the instant claims and that the secondary reference neither discusses anilinoquinazolines nor establishes a pertinent relationship between -CH₃ groups and -H atoms.

In response to applicant's argument that the secondary reference neither discusses anilinoquinazolines nor establishes a pertinent relationship between -CH₃ groups and -H atoms, the examiner reiterates that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. {See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981)}.

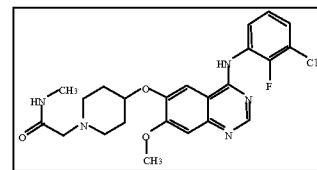
Similarly, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies, namely selection of the reference compound as a lead compound possessing anti-tumor activity, is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. {See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)}.

Moreover, in response to applicant's argument that there is no rationale to modify the

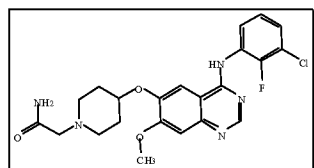
Art Unit: 1624

reference example to achieve the species of the instant claims and that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is, in a sense, necessarily a reconstruction based upon hindsight reasoning. Provided it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and excludes knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. {See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971)}.

As discussed in the *Non-Final Rejection*, mailed on August 19, 2008, the only difference between the instantly recited 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{{1-(*N*-methoxycarbonylmethyl)piperidin-4-yl}oxy}quinazoline,



shown to the right above, and Bradbury's 2-(4-(4-(3-chloro-2-fluorophenyl-amino)-7-methoxyquinazolin-6-yloxy)piperidin-1-yl)acetamide, shown to the left below, is the instantly recited



substituted quinazolinamine has an *N*-methoxycarbonylmethyl substituent on the nitrogen of the piperidine ring, whereas Bradbury's substituted quinazolinamine has a carbamoylmethyl substituent on the nitrogen of the piperidine ring.

The examiner highlights that Bradbury, et al. (WO 03/082831) teaches substituted quinazolinamines as anti-tumor agents [p. 1, lines 1-3]. Furthermore, in the genus disclosure, Bradbury teaches that substituents attached to the piperidine ring may be *N*-methoxycarbonyl [p. 14, line 33, *N*-C₁₋₆alkylcarbamoyl].

Consequently, one having ordinary skill in the art, at the time this invention was made, would have been highly motivated to utilize the teachings of Bradbury and replace the

Art Unit: 1624

carbamoylmethyl substituent on the nitrogen of the piperidine ring in Bradbury's substituted quinazolinamines, with an alternatively usable *N*-methylcarbamoyl substituent, with a reasonable expectation of success and similar therapeutic activity.

New Specification Objection

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art (including information disclosed under 37 CFR 1.97 and 1.98).
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825).

Applicant is advised to format the specification according to 37 CFR 1.77(b) above.

Art Unit: 1624

Revisions should particularly include and/or address sections (b-i). Appropriate correction is required.

New Specification Objection - Title

Applicant is reminded of the proper content of the title of the invention.

The title of the invention should be brief, but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a) and MPEP § 606.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In the revised title, the examiner suggests including the alleged utility possessed by the compounds applicants regard as their invention.

Allowable Subject Matter

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

Art Unit: 1624

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**